EUROPEAN
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ANNEX

ANNEX

to the

COMMISSION IMPLEMENTING REGULATION (EU) .../...

establishing a list of antimicrobials which shall not be used in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 of the European Parliament and of the Council or which shall only be used in accordance with those articles subject to certain conditions

ANNEX

Antimicrobials or groups of antimicrobials	Conditions on the use in accordance with Articles 112 and 113 of Regulation (EU) 2019/6
Aminopenicillins in combination with beta-lactamase inhibitors	(1) In the cases of use of aminopenicillins in combination with beta-lactamase inhibitors for indications not included in the terms of the marketing authorisation of a medicinal product authorised in the Union and containing those antimicrobials, the veterinarian responsible shall prescribe those antimicrobials based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) aminopenicillins in combination with beta-lactamase inhibitors are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) Aminopenicillins in combination with beta-lactamase inhibitors shall not be used in accordance with Article 113 of Regulation (EU) 2019/6 in poultry.
Third- and fourth-generation cephalosporins	(1) In the cases of use of third- or fourth-generation cephalosporins for indications not included in the terms of the marketing authorisation of a medicinal product authorised in the Union and containing those antimicrobials, the veterinarian responsible shall prescribe those antimicrobials based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) third- or fourth-generation cephalosporins are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) The use shall be limited to administration to individual animals only. This condition shall not apply to the use in accordance with Article 112 of Regulation (EU) 2019/6 in aquatic animals kept in closed water tanks. (3) Third- and fourth-generation cephalosporins shall not be used in accordance with Article 113 of Regulation (EU) 2019/6 in

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	poultry. (4) In the cases of treatment of salmonellosis in animals other than poultry, the use in accordance with Article 113 of Regulation (EU) 2019/6 shall be limited to injectable medicinal products administered to individual animals with potentially life-threatening infections.
Polymyxins	(1) In the cases of use of polymyxins for indications not included in the terms of the marketing authorisation of a medicinal product authorised in the Union and containing those antimicrobials, the veterinarian responsible shall prescribe those antimicrobials based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) polymyxins are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) For salmonellosis, polymyxins shall not be used in accordance with Article 113 of Regulation (EU) 2019/6 in poultry. (3) For salmonellosis in animals other than poultry, veterinary medicinal products, which are authorised for oral administration to groups of animals, may be used in accordance with Article 113 of Regulation (EU) 2019/6 for treatment of individual animals only. (4) In each of the following cases the administration of the medicinal product shall be limited to individual animals only: (a) use of a veterinary medicinal product in accordance with Article 112 or 113 of Regulation (EU) 2019/6 via a route of administration not included in the terms of its marketing authorisation; (b) use of a medicinal product for human use authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004; (c) use of a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription.
Amphenicols	In the cases of use of amphenicols for indications not included in the terms of the marketing authorisation of a medicinal product authorised

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	in the Union and containing those antimicrobials, the veterinarian responsible shall prescribe those antimicrobials based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) amphenicols are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective.
Quinolones (including fluoroquinolones)	(1) In the cases of use of quinolones (including fluoroquinolones) for indications not included in the terms of the marketing authorisation of a medicinal product authorised in the Union and containing those antimicrobials, the veterinarian responsible shall prescribe those antimicrobials based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) quinolones (including fluoroquinolones) are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) For salmonellosis, quinolones (including fluoroquinolones) shall not be used in accordance with Article 113 of Regulation (EU) 2019/6 in poultry. (3) For metaphylaxis of salmonellosis, quinolones (including fluoroquinolones) shall not be used in accordance with Article 113 of Regulation (EU) 2019/6 in animals other than poultry. (4) In the cases of treatment of salmonellosis in animals other than poultry, the use of quinolones (including fluoroquinolones) in accordance with Article 113 of Regulation (EU) 2019/6 shall be limited to injectable medicinal products administered to individual animals with potentially life-threatening infections. (5) In each of the following cases the administration of the medicinal product shall be limited to individual animals only: (a) use of a veterinary medicinal product in accordance with Article 112 or 113 of Regulation (EU) 2019/6 via a route

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	of administration not included in the terms of its marketing authorisation; (b) use of a medicinal product for human use authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004; (c) use of a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription.
Rifamycins except rifaximin	(1) The veterinarian responsible shall prescribe rifamycins except rifaximin, based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) rifamycins are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) The use shall be limited to administration to individual animals for treatment of mycobacteria or multidrug-resistant staphylococci only in combination with other antimicrobials likely to be clinically effective.
Rifaximin	In the cases of use of medicinal products, other than veterinary medicinal products authorised in the Union, the veterinarian responsible shall prescribe rifaximin, based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) rifaximin is likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective.
Substances used solely to treat tuberculosis or other mycobacterial diseases	(1) The veterinarian responsible shall prescribe substances used solely to treat tuberculosis or other mycobacterial diseases, based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) those substances are likely to be clinically effective; (b) preferable antibiotics in accordance with the

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	Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) The use shall be limited to administration to individual animals only.
Riminofenazines	(1) The veterinarian responsible shall prescribe riminofenazines, based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) riminofenazines are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable at the Member State concerned, would not be clinically effective. (2) The use shall be limited to administration to individual animals only for treatment of mycobacteria only.
Pseudomonic acids	(1) The veterinarian responsible shall prescribe pseudomonic acids, based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that: (a) pseudomonic acids are likely to be clinically effective; (b) preferable antibiotics in accordance with the Categorisation of antibiotics in the European Union of the European Medicines Agency, or in accordance with stricter rules applicable in the Member State concerned, would not be clinically effective. (2) Pseudomonic acids may only be used where the following conditions are met: (a) the medicinal product is to be used for the treatment of infections with methicillin-resistant *Staphylococcus aureus* or methicillin-resistant *Staphylococcus pseudintermedius*; (b) the use of veterinary medicinal products authorised for the treatment for staphylococcal infections via the topical route of administration has not been clinically effective; (c) the medicinal product is to be administered to individual animals;

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	(d) the medicinal product is to be administered via the topical route of administration. (3) Pseudomonic acids shall not be used for routine decolonisation of methicillin-resistant *Staphylococcus aureus* or methicillin-resistant *Staphylococcus pseudintermedius*.
Remdesivir	Remdesivir may only be used in accordance with Article 112 of Regulation (EU) 2019/6 for the treatment of feline infectious peritonitis.
Echinocandins	(1) The veterinarian responsible shall prescribe echinocandins based, where possible, on prior target pathogen identification and antimicrobial susceptibility testing. The antimicrobial susceptibility testing shall demonstrate that those antimicrobials are likely to be clinically effective. (2) Echinocandins may only be used where the following conditions are met: (a) the medicinal product is to be administered to individual animals; (b) the medicinal product is to be used for the treatment of invasive aspergillosis or candidiasis; (c) the medicinal product is to be administered as a last resort.
Amphotericin B	In the case of treatment of leishmaniasis, or of other diseases in animals in regions where leishmaniasis is endemic, amphotericin B may be used only as a last resort.